DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 25, 2015

Medicrea International S.A.
Ms. Audrey Vion
Regulatory Affairs Manager
14 Porte Du Grand Lyon
01700 Neyron
France

Re: K142798
Trade/Device Name: PASS LP Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, KWP, MNI, OSH
Dated: March 5, 2015
Received: March 9, 2015

Dear Ms. Vion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k142798

Device Name

PASS LP Spinal System

Indications for Use *(Describe)*

The PASS LP Spinal System includes a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

Fractures
Dislocation
Failed previous fusion (Pseudoarthrosis)
Spinal stenosis
Degenerative spondylolisthesis with objective evidence of neurological impairment
Spinal deformations such as scoliosis or kyphosis.
Loss of stability due to tumors.

The PASS LP Spinal Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also includes hooks and rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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I. 510(K) SUMMARY

1. DEVICE SUBMITTER

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Date Prepared: 03/05/2015

2. DEVICE

Name of Device: PASS LP Spinal System

Common or Usual Name: Spinal Lumbar Fixation System

Classification Name:

- ✓ orthosis, spinal pedicle fixation per MNI 888.3070
- ✓ orthosis, spondylolisthesis spinal fixation per MNH 888.3070
- ✓ appliance, fixation, spinal interlaminal per KWP 888.3050
- ✓ pedicle screw spinal system, Adolescent Idiopathic Scoliosis per OSH 888.3070

Regulatory Class: II

Product Code: MNI, MNH, KWP and OSH

3. PREDICATE DEVICE

PASS LP Spinal System, K123138.
This predicate has not been subject to a design-related recall.
No reference device was used in this submission.

4. DEVICE DESCRIPTION

The PASS LP Spinal System is designed to contribute to correction and surgical stabilization of the thoracic, lumbar and sacral spine.

The system consists of pedicle screws, hooks, sacral plates, iliac screws, clamps, rods, nuts, rod plates and crosslink components. It can be used for single or multiple level fixations. Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 or cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

A subset of PASS LP Spinal System components may be used for posterior pedicle screw fixation in pediatrics cases. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, sacral plates, iliac screws, clamps, nuts and crosslink components. The PASS LP components can be rigidly locked into a variety of configurations, with each construct being tailored made for the individual case.

The purpose of this submission is to extend to the PASS LP Spinal System, with the addition of new components: 'Monoaxial Pedicle Screws' and 'Rod Connectors'.

5. INDICATIONS FOR USE

The PASS LP Spinal Systems include a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fractures
- Dislocation
- Failed previous fusion (Pseudoarthrosis)
- Spinal stenosis
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Spinal deformations such as scoliosis or kyphosis.
- Loss of stability due to tumors.

The PASS LP Spinal System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.
The PASS LP also includes hooks and rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The Indications For Use statement for the PASS LP Spinal System is identical to the predicate device. Both the subject and predicate device have the same intended use for the treatment of acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the features and characteristics of the PASS LP Spinal System to its predicate device.

Device	**PASS LP Spinal System – New Components**	**PASS LP Spinal System**
510(k) number	NA	K123138
Intended use		
Thoracic, Lumbar spine	Yes	Yes
Posterior Approach	Yes	Yes
Design		
Rod Connectors		
Rod diameters	Ø5.5 or Ø6mm	Ø5.5 or Ø6mm
Bone anchorage connection	Polyaxial	Polyaxial
Connector Angulation	45° in the frontal plane	50° in the frontal plane
Color Coded	Yes	Yes
Shape	Rod part pre-bent (radius 135.50mm)	Pre-bent rod (radius 135.50mm)
Monoaxial Pedicle Screws		
Screw Diameters	Ø4.5mm to Ø7.5mm	Ø4.5mm to Ø7.5mm
Screw Lengths	From 25mm to 60mm with 5mm increment	From 25mm to 60mm with 5mm increment
Color Coded	Yes	Yes
Shape	Conical thread Spherical head for connection with other PASS LP components Breakable threaded part for Nut tightening	Conical thread Spherical head for connection with other PASS LP components Breakable threaded part for Nut tightening
Threaded Extension	Long or short threaded extension	Long threaded extension
Materials		
PASS LP Additional Components	Titanium alloy (Ti-6Al-4V ELI, following standards ASTM F136 and ISO 5832-3)	Titanium alloy (Ti-6Al-4V ELI, following standards ASTM F136 and ISO 5832-3)

Material composition is identical to other MEDICREA® INTERNATIONAL products that have been cleared via the 510(k) process.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the PASS LP system was conducted in accordance with the FDA blue book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- ✓ *Cytotoxicity*
- ✓ *Sensitization*
- ✓ *Irritation*
- ✓ *Systemic toxicity*
- ✓ *Pyrogen Testing*

According to the standard **ISO 10993-1**, the PASS LP Spinal System is defined as implantable device in contact with tissue and bone and as a permanent contact with the patient.

*For chemical composition, the material conform to*Ti-6Al-4V ELI, following standards ASTM F136 and ISO 5832-3.

Mechanical testing

When applicable, the tests performed on the additional components (dynamic axial compression according to ASTM F1717) indicate that the products are as mechanically sound as other devices commercially available.

Clinical study

No clinical studies were performed.

Animal study

No animal studies were performed.

8. CONCLUSION

MEDICREA® INTERNATIONAL S.A. PASS LP Spinal System is substantially equivalent to its predicate device in terms of indications for use, design, material and function.